

**Remarks**

By the foregoing amendments, claim 1 is amended and claim 10 has been canceled. No new matter is added. Support for the amendment to claim 1 can be found throughout the specification, and specifically, for example, on page 15, lines 20-22, and on page 19, lines 9-13, and lines 20-25.

Reconsideration and allowance of the application are respectfully requested.

**Claim Rejections – 35 U.S.C. § 112, second paragraph**

The Action rejects claims 1-8, 10, 14, and 19-21 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which is regarded as the invention. In particular, the Action alleges that the recitation of the phrase “the bone replacement material is in a state such that a number of pellets of the bone replacement material are introduced into a cavity of the bone defective part and are aggregated therein” is indefinite because it positively recites a method step but the claim is directed to a bone replacement material, not a method of implanting the material.

In response, to advance prosecution of the application and without expressing agreement or acquiescence to the propriety of the rejection, Applicants amend claim 1 by deleting the phrase “the bone replacement material is in a state such that a number of pellets of the bone replacement material are introduced into a cavity of the bone defective part and are aggregated therein.”

In view of the foregoing, Applicants request that the rejection under 35 U.S.C. 112, second paragraph, be withdrawn.

Claim Rejections – 35 U.S.C. § 103

The Action rejects claims 1-8, 10, 14, and 19-21 under 35 U.S.C. § 103(a) as allegedly unpatentable over Garrison et al. (U.S. Published Application No. 2005/0038517) in view of Shimp (U.S. Published Application No. 2004/0052829) in further view of Kim et al. (U.S. Patent No. 5,645,596) and in further view of Tofighi et al. (U.S. Published Application No. 2003/0120351).

Applicants submit that Garrison et al., Shimp, Kim et al., and Tofighi et al. fail to teach or suggest all the elements of the claimed invention. For example, the cited art fails to teach or suggest, at least, a pellet “wherein the pellet has a roughly polyhedral shape and, wherein the pellet is defined by a plurality of surfaces including a pair of opposite, non-parallel surfaces, one of the opposite, non-parallel surfaces being inclined at a predetermined angle with respect to the other of the opposite, non-parallel surfaces, and wherein the predetermined angle is in the range of 20 to 40°.” Instead, for example, Garrison et al. discloses a tapered wedge 102 (1) that can be introduced into the bone structure, wherein the wedge has a tapered side with respect to the driven side 152 (see abstract and Figure 3). Applicants note that, when measured, the angle of the tapered side with respect to the driven side 152 is 57 to 58°.

Garrison et al. teaches that the tapered wedge 102 (1) includes a tapered side 144 located between the distal ends of the leading and lagging sides 140 and 142, which forms a point 146 (see page 4, paragraph [0048]). Garrison et al. also discloses that when tapered wedges 102 (1) are placed back-to-back, forming a wedge pair 132, the two points 146 form a pointed nose 148 (*Id.*). This pointed nose 148 facilitates the insertion of the wedge pair 132 between another wedge pair 132 as shown in Figure 5. It is apparent that Garrison et al. fully considered the shape of the tapered wedge 102 (1) and how the pairing of the wedges into a wedge pair 132

assists in the implantation of the wedges into the vertebrae (page 4, paragraph [0045] and Figure 5). In particular, the tapered wedges 102 (1) are introduced into the vertebrae and form a wedge stack 134 (page 4, paragraph [0045]). Applicants submit that the wedge shape and specific angles of tapered wedge 102 (1) (i.e., 57 to 58°) appear to be important features for wedge stacking. Applicants submit that there is nothing in Garrison et al. that would provide any reason for modifying the angle of the tapered wedge from 57 to 58°, to a range of 20 to 40°. In this regard, Applicants note that Garrison et al. does not disclose any other sizes or angles of the tapered wedge 102 (1). Applicants submit that Garrison et al. fails to teach or suggest a predetermined angle range of 20 to 40°. Furthermore, Applicants note that Shimp, Kim et al., and Tofighi et al. fail to remedy this deficiency in Garrison et al. That is, they fail to provide any reason for modifying Garrison et al.'s disclosure to narrow the angle to 20 to 40°.

Applicants further submit that in the present invention, advantages are realized when the predetermined angle of the pellet is in the range of 20 to 40°. For example, when the angle exceeds 40°, sharp protrusions form on the bone replacement material which increase the likelihood of chipping. When the angle is less than 40°, the sharp protrusions are prevented and the likelihood of chipping decreases. Furthermore, Applicants note that the tapered wedges 102 (1) of Garrison et al., having an angle of 57 to 58°, form wedge stacks 134 in the vertebrae and cannot be pushed out in various directions by the wedge driver from the cannula 104 (page 4, paragraph [0045] and Figures 5, 13-18).

Applicants further submit that none of the cited documents teaches or suggests, at least, a "pellet of the roughly polyhedral shape is defined by a plurality of edges having different lengths, in which the length of the longest edge is in the range of 5 to 10 mm and the length of the shortest edge is in the range of 2 to 5 mm, wherein the

volume of each pellet of the bone replacement material is in the range of 13 to 239 mm<sup>3</sup>.” In particular, Shimp, which the Action relies on to teach the claimed pellet lengths and the claimed volume, only teaches a support element (pellet) that can range in size from 50 microns up to 4 mm. In calculating the alleged volume of 64 mm<sup>3</sup> for the support element (pellet), the Action uses 4 mm. This requires that the longest edge and the shortest edge of the support element (pellet) have a range of 4 mm. However, claim 1 recites the pellet’s dimensions as “having different lengths” wherein the “length of the longest edge is in the range of 5 to 10 mm.” As Shimp fails to disclose, at least, two differing lengths, as well as the range of the longest edge, Applicants submit that Shimp fails to teach the claimed pellet dimensions. Garrison et al., Kim et al., and Tofighi et al. fail to remedy Shimp’s deficiency. Thus, Applicants submit that Garrison et al., Shimp, Kim et al., and Tofighi et al. fail to teach or suggest all the features of the claimed invention.

In view of at least the above, Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

## CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,  
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